

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

# PCT

To:  
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Ufficio Internazionale Brevetti  
Dott. Prof. Franco Cicogna  
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WRITTEN OPINION

(PCT Rule 66)

Date of mailing (day/month/year) <span style="float: right;">11/06/2004</span>	
Applicant's or agent's file reference 03/111/EST	<b>REPLY DUE</b> within 2 / 00 months/days from the above date of mailing
International application No. PCT/IT03/00419	International filing date (day/month/year) 03/07/2003
Priority date (day/month/year) 03/07/2003	
International Patent Classification (IPC) or both national classification and IPC A61K7/16	
Applicant BETAFARMA S.P.A. et al.	

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.
 

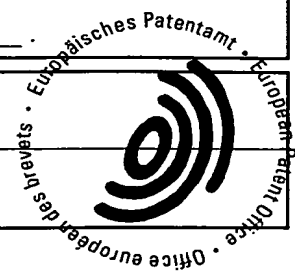
**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also** For an additional opportunity to submit amendments, see Rule 66.4.  
 For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.  
 For an informal communication with the examiner, see Rule 66.6.

**If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 03/11/2005

Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Examiner  Formalities officer (incl. extension of time limits) Tel. (+49-89) 2399 2828
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**I. Basis of the opinion**

1. The basis of this written opinion is the application as originally filed.

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability**

1. In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claims references).
2. If amendments are filed, the applicant should comply with the requirements of Rule 66.8 PCT and indicate the basis of the amendments in the documents of the application as originally filed (Article 34 (2) (b) PCT) otherwise these amendments may not be taken into consideration for the establishment of the international preliminary examination report. The attention of the applicant is drawn to the fact that if the application contains an unnecessary plurality of independent claims, no examination of any of the claims will be carried out.

NB: Should the applicant decide to request detailed substantive examination, then an international preliminary examination report will normally be established directly. Exceptionally the examiner may draw up a second written opinion, should this be explicitly requested.

Re: International Application No. PCT/IT03/00419  
filed on 03/07/2003 in the name of  
BETAFARMA S.P.A. et al.

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Sir,

This is in response to the PCT Written Opinion (PCT Rule 66) mailed on 11/06/2004.

From item 1 of the Office Letter, Applicant has noted that in light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claims references).

For overcoming the above rejection grounds, Applicant has cancelled claims 1 to 10 and has submitted new claims 1 to 8, for patentably distinguishing Applicant's invention over the prior art documents either individually or in combination.

From the new main claim, the gist of the invention should be envisaged in the fact that Applicant's

antibacteric composition comprises at least an oil phase in which antiseptic substances exclusively soluble in the oil phase are dissolved, and an aqueous phase in which water soluble antibacteric substances are dissolved, thereby said composition is adapted to form on an user teeth an oil film which cannot be easily removed by water rinsing.

It is believed that the new main claim, which is substantially a combination of previous claims 1 and 2, is actually novel and non obvious with respect to the prior art documents.

In fact, the document WO 96/15770 discloses a composition comprising at least one bitter quaternary ammonium salt and at least one bitter essential oil combined with a surfactant in a suitable carrier solvent such that the bitter tasting components are effectively taste masked. This composition is very different from that taught by the Applicant in new main claim.

The document WO 99/22703 discloses a composition including an amphiphilic lipid carrier in the form of colloidal composition which can include a micellar aggregate or mixed micelles dispersed in a continuous aqueous phase: also this composition is very different from that taught by the Applicant in the new main claim.

The document 0 579 383 discloses an oral composition mouthwash containing an aqueous vehicle including an alcohol, and a substantially water-insoluble non cationic antibacterical antiplaque agent: thus, it should be apparent that also this prior composition is

very different from that taught by the Applicant in the new main claim.

The document EP 1 312 354 discloses an oral care composition comprising diglycerol used as a humectant in the composition: no diglycerol is contained in Applicants composition. Thus, it is respectfully submitted that also this prior art document does not anticipate Applicant's main claim.

The document EP 07 02 5735A discloses an oral composition which, as its main component, contains cetyl piridinum chloride: thus, also this prior composition is very different from that taught by the Applicant in the new main claim.

The document US 5 294 431 discloses an oral composition comprising an aqueous vehicle with a substantially water-insoluble and non-cationic antibacterial antiplaque agent, in particular triclosan: thus, it should be apparent that also this prior composition does not anticipate the teachings of Applicant's main claim.

The document 5 328 682 discloses a composition for mouthwashes which has an abrasive nature, very different from the composition taught by Applicant in the new main claim.

The document 5 416 075 discloses an oil-in-water emulsion comprising an aqueous phase, an oil phase and an emulsifier system which comprises an amphiphatic compound including a biospecific moiety at the head end of its hydrophilic group. Thus, also this composition is very different from that taught by the

Applicant in the new main claim.

The document US 2 002/0081267 discloses an oral composition based on a surfactant, emulsifier and triclosan: thus, also this prior composition is very different from that taught by the Applicant in the new main claim.

The document 5 401 496 discloses an oral composition including a synthetic oil containing an ester of an alcohol and an aliphatic acid of at least six carbon atoms: thus, it should be apparent that also this composition is very different from that taught by the Applicant in the new main claim.

The document EP 0 244 363 discloses an oral composition including a synergistic combination of a bis-biguanido hexane compound and a mixture of at least two essential oils: thus, also this prior composition does not anticipate Applicant's main claim.

The document EP 0 528 457 discloses an oral composition containing an oil-in-water emulsion, wherein the oil phase of the emulsion includes an amino alkyl silicone and a lipolic compound and the aqueous phase include an emulsifier: thus, also this composition is very different from that taught by the Applicant in the new main claim.

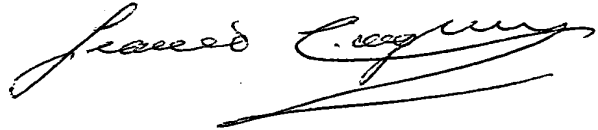
Finally, the document De 42 07 704 discloses an oral composition which comprises a methyl silicone oil and polydimethyl xiloxanes: thus, also this composition is very different from that taught by the Applicant in the new main claim.

In this connection, Applicant desires to draw the attention of the Examiner on the fact that none of the prior art documents teaches or addresses to provide such a composition which is adapted to form on an user teeth an oil film which cannot be easily removed by water rinsing, as, on the contrary, is taught by the Applicant in the new main claim.

Accordingly, it is respectfully submitted that Applicant's main claim, and the other claims dependent thereon should have patentable merits over the prior art documents.

In view of the foregoing discussion, a favorable prosecution of the Application is respectfully urged.

Respectfully submitted

A handwritten signature in dark ink, appearing to read "James C. [unclear]", with a long horizontal flourish extending to the right.

Encl.: New claim 1 to 8 pages 5 and 6

**CLAIMS**

1. An antibacteric composition, particularly designed to be used as a mouthwash  
5 composition for sanitizing the buccal cavity, characterized in that said antibacteric composition comprises at least an oil phase in which antiseptic substances exclusively soluble in said oil phase are dissolved, and an aqueous phase, in which water  
10 soluble antibacteric substances are dissolved, thereby said composition is adapted to form on an user teeth an oil film which cannot be easily removed by water rinsing.

2. A composition, according to claim 1,  
15 characterized in that said aqueous phase varies from about 60% w/w to about 95% w/w.

3. A composition, according to claim 1, characterized in that said water soluble antibacteric substances comprise moistening agents, alcohols,  
20 fluorinated salts, sweetening substances, coloring substances, pH adjusters and so on.

4. A composition, according to claim 3, characterized in that said moistening substances are selected from glycerol, sorbitol, xylitol, glycoles,  
25 said alcohols being selected from ethyl alcohol and propyl alcohol and said sweetening substances being selected from saccharine and aspartames.

5. A composition, according to claim 1, characterized in that said oil phase varies from  
30 about 5% w/w to about 40% w/w.

6. A composition, according to claim 1, characterized in that said oil phase comprises vegetable oils, mineral oils, aliphatic esters,



aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons.

7. A composition, according to claim 1, characterized in that said oil phase comprises  
5 aromatizing oils.

8. A composition, according to one or more of the preceding claims, characterized in that said composition further comprises an emulsifying system of an oil in water (O/W) type, adapted to form stable  
10 emulsions.